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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MARY COLLINS, ET AL.

Application No.: 09/714,792

Filed: November 16, 2000

For: ANTIBODIES TO HUMAN IL-13bc  
AND METHODS OF THEIR USE IN  
INHIBITING IL-13 BINDING

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: Examiner: Fozia M. Hamud  
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: Group Art Unit: 1647  
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)  
: December 23, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

RESPONSE TO ADVISORY ACTION  
AND REQUEST FOR NEW OFFICE ACTION

Sir:

Applicants received an "Advisory Action" dated December 7, 2004. The propriety of that paper is unclear; the immediately previous paper dated April 20, 2004 (paper No. 041604) was not a "final" Office Action. That is, as understood, there is no basis for an Advisory Action and Applicants respectfully request that the December 7, 2004 paper be withdrawn and a new Office Action issued instead.

As to the merits of the Office Action, the December 7, 2004 paper states that claims 18, 41, 46-49, 51, 53-57, 59, 61-65, 67, 69, 78-81, 83, 85-94 and 96-104 are allowed. The sole remaining issue is the rejection of claims 105-131 as failing to be supported by the specification as filed. Specifically, the Examiner states:

"The new claims 105-131 are not enabled under 35 U.S.C. 112, first paragraph, because the instant specification does not disclose a method of treating cancer by administering antibodies that bind to human IL-13bc of SEQ ID NO:4.

Applicants submit post filing date references that demonstrate that IL-13Rbc is expressed in high levels in cancers such as glioma or neuroblastomas and that anti-IL-13 Rbc antibodies might be useful. However, treating these specific cancers is new matter that was never disclosed by the instant specification at the time of filing." (Emphasis added.)

Frankly speaking, the Examiner's basis for this is not understood either. That is, Applicants quite agree that treating "these specific cancers" would be new matter but the fact remains that Applicants do not claim treating those specific cancers; claims 105-131 relate only to treatment of cancers generally. Written description of those claims was discussed in Applicants' September 10, 2004 amendment.

For the Examiner's convenience, such is reiterated below. In the previous amendment, Applicants invited the Examiner's attention to specification page 12. Lines 16-26 therein state:

"IL-13bc protein (particularly soluble IL-13bc proteins) and IL-13R inhibitors may be useful in treatment or modulation of various medical conditions in which IL-13 is implicated or which are effected [sic] by the activity (or lack thereof) of IL-13 (collectively "IL-13-related conditions"). IL-13-related conditions include ... cancer."

Respectfully submitted, such plainly satisfies 35 U.S.C. 112, first and second paragraphs with respect to the subject matter of claims 105-131. That is, the inventive step lay in the identification of the antibodies of the allowed claims and Applicants' recognition that such exhibit anti-cancer activity as discussed in the specification. However, it does not require inventive activity to formulate those antibodies in dosage forms.<sup>1/</sup> Accordingly, withdrawal of this rejection is respectfully requested.

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<sup>1/</sup> However, if it will be helpful to the Examiner and/or for completeness of the record, Applicants will gladly provide a Declaration under rule 131 as to the sufficiency of such teaching for enabling the practice of the pending claims.

Regarding a formal matter, the Examiner considered four of the five references cited in the September 10, 2004 Information Disclosure Statement but did not indicate that the Husain, et. al., "Interleukin-13 Receptor as a Unique Target for Anti-Glioblastoma Therapy", *Int. J. Cancer*, Vol. 92 (2001), pages 168-175 reference was considered. Confirmation that such too, was considered and placed of record herein is respectfully requested in the next Patent Office communication.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 18, 41, 46-49, 51, 53-57, 59, 61-65, 67, 69, 78-81, 83, 85-94 and 96-131 are presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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